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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,111	09/16/2003	Dolores Schendel	1406/468	6128

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,111	SCHENDEL ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-30 and 32-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-26,33-42 and 44-47 and 49* is/are allowed.

6)☒ Claim(s) *27-30,32,43 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/17/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 26, 27, 35 and 48 have been amended. Claims 23-30 and 32-49 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 27, 28, 30, 32, 43 and 48 under 35 U.S.C. 102(b) as being anticipated by Philip et al (Cancer Gene Therapy, 1998, Vol. 5, pp. 236-246) is maintained for reasons of record.

Clam 27 is drawn to a pharmaceutical composition comprising antigen-presenting cells into which protein and or peptide or RNA or DNA or cDNA encoding said proteins and/or peptides have been introduced, wherein the APC are semi-allogeneic and HLA-haploidentical with respect to those of the patient, wherein the HLA-haploidentical APC have class I and class II molecules in common with the patient and wherein said proteins and/or peptides are over expressed in tumor cells of a patient with a tumor disease or are derived from tumor cells from the patient. Claim 28 embodies the composition of claim 27, wherein the proteins, peptides, RNA or DNA or cDNA encoding said proteins or peptide are selected from carcinomas, hematopoietic tumor cells, mesenchymal tumor cells, epithelial tumor cells, ectodermal tumor cells, and embryonic tumor cells from undifferentiated tissue. Claim 30 embodies the composition of claim 27 wherein the HLA-haploidentical APC are dendritic cells or macrophages. Claim 32 embodies the composition of claim 27 that is a vaccine. Claim 43 embodies the composition of claim 28 wherein the carcinomas are ovarian, mammary and renal, the hematopoietic cells are leukemias and lymphomas, the mesenchymal tumor cells are sarcomas, the ectodermal tumors are melanomas and the embryonic tumors are blastomas and teratomas. Claim 48 embodies the composition of claim 27, wherein the HLA-haploidentical APC of the donor have a HLA-haplotype that is 50% identical to that of the patient.

It is noted that claims 27, 28, 30, 32, 43 and 48 are drawn to a composition. Thus, the recitation of "the patient" in claim 27 implies an intended use for said composition which does not provide patentable weight when distinguishing the claim from the prior art. It is also noted that the prior Office action had a typographical error in the identification of claim 48 as claim 47, which is drawn to the method rather than the composition.

Philip et al disclose the expression of MART-1 cDNA in human dendritic cells prepared from healthy individuals as well as peptide-loaded dendritic cells (page 237 under "Preparation of DC", "Plasmid constructs and preparation", page 238 under "Peptide-loaded DC). The dendritic cells of Philip et al meets the specific embodiments of the instant claims because they are inherently "haploidentical" to an appropriate recipient and possess an HLA-haplotype 50% identical to an appropriate recipient. Furthermore, the MART-1 antigen is over expressed in melanoma, which meets" the limitations of claims 28 and 43.

The rejection of claims 27, 28, 30, 32, 43 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al (U.S. 2002/0123479) are maintained for reasons of record.

Song et al disclose dendritic cells comprising an expression vector which direct expression of antigens associated with cancers, including breast, colon, and brain cancer, melanoma and leukemias (paragraph [0007] and paragraph [[0010]. Song et al disclose a method of treatment of cancer (paragraph [0006]) comprising the administration of a dendritic cell population transduced ex vivo (paragraph [0017]).

The ex vivo transduced dendritic cells of Song et al meets the specific embodiments of the instant claims because they are inherently "haploidentical" to an appropriate recipient and possess an HLA-haplotype 50% identical to an appropriate recipient.

Applicant argues that the cited references of Philip et al and Song et al do not provide for semi-allogeneic HLA-haploidentical cells with respect to those of a patient with a tumor disease. Applicant quotes the MPEP section 2112 stating that inherency cannot be based on a certain result or characteristic which may occur, rather than a result or characteristic which is necessarily present. This has been considered but not found persuasive. In the instant case, the dendritic cells of Philip et al and Song et al would necessarily be semi-allogeneic and HLA-haploidentical

with "a patient" having a tumor disease. The instant claims drawn to a composition do not serve to specify the specific HLA identity of "a patient".

Applicant's argument regarding the examiner use of "an appropriate recipient" are evidence that the cells of Philip et al and Song et al are not inherently haploidentical. This has been considered but not found persuasive. The use of "appropriate patient" was to simply differentiate from "all patients".

Applicant argues from page 12, second full paragraph to page 14, second full paragraph, that the cells of Philip et al, and Song et al do not meet the limitation of semi-allogeneic and HLA-haploidentical. This has been considered but not found persuasive. To summarize, applicant states that in the instant invention HLA-A, B, C, DR, DQ and DP are encoded by an allele in common with those of the patient (page 13, first full paragraph). Applicant alleges that the examiner does not understand the implications of semi-allogeneic and HLA-haploidentical. In response, it is pointed out that "relative to" the HLA-haploidentity of a patient with the tumor disease does not serve to exclude the dendritic cells taught by either Philip et al or Song et al because the actual patient is not part of the composition claim in contrast to the claims drawn to a method.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 27-30, 32, 43 and 48 under 35 U.S.C. 103(a) as being unpatentable over Philip et al (Cancer Gene therapy, 1998, Vol. 5, pp. 236-246) in view of Cohen (WO98/33527, cited in a prior action) and Warnier et al (WO 98/58956, cited in a prior action) is maintained for reasons of record.

Claim 29 embodies the composition of claim 27 wherein the proteins, peptides, RNA, DNA, or cDNA are derived from several different tumor cell lines.

Cohen et al teach the incorporation of DNA or RNA encoding for at least one tumor antigen introduced into an antigen presenting cell (page 30, lines 1-3 and 7-8) as well as the transduction of tumor genomic DNA obtained from a tumor cell line (page 8, lines 8-11 and page 30, lines 11-16). Cohen does not specifically teach using polynucleotides or polypeptides from several different tumor cell lines, although Cohen et al does teach using "at least one" tumor antigen which is suggestive of using multiple tumor antigens.

Warnier et al teach that tumors express a set of tumor antigens, of which only certain subsets may be expressed in the tumor of any given patient and the desirability of having antigen-presenting cells expressing "polytopes" comprising multiple epitopes on tumor antigens in order to reflect a boarder spectrum of tumor associated antigens (page 20, line 31 to page 21, line 7)

It would have been prima facie obvious at the time the clamed invention was made to pulse or transduce the dendritic cells of Philip et al using peptides or cDNA from more than one tumor cell line. One of skill in the art would have been motivated to do so by the teachings of Cohen et al on the incorporation of DNA or RNA encoding at least one tumor antigen introduced into an APC from "at least one" tumor cell line which is suggestive of more than one cell line and the teachings of Warnier et al on the restricted expression of antigen on patient tumors. One of skill in the art would have been motivated to include the antigens from several different tumor cell lines in order to insure that the antigen–presenting cell would provide antigens which were expressed on actual patient tumors.

Applicant argues that Cohen et al and Warnier et al fail to remedy the deficiencies of Philip et al. applicant argues that Cohen et al also fails to suggest the use of multiple tumor antigens based on the wording of "at least one". This has been considered but not found persuasive for the reasons set forth above. Further, using "at least one" tumor antigen plainly includes the use of more than one tumor antigen.

All other rejections and objections as set forth or maintained in the prior Office action are withdrawn.

. Claims 23-26, 33-42, 44-47 and 49 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571)272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643